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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|-------------|----------------------|---------------------|------------------|
| 09/980,727 | 07/08/2002 | Hubert Rein | 228.1010 | 8812 |
| 23280 | 7590 | 04/05/2005 | EXAMINER | |
| DAVIDSON, DAVIDSON & KAPPEL, LLC | | | OH, SIMON J | |
| 485 SEVENTH AVENUE, 14TH FLOOR | | | | |
| NEW YORK, NY 10018 | | | ART UNIT | PAPER NUMBER |
| | | | 1615 | |

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/980,727 | REIN ET AL. | |
| | Examiner | Art Unit | |
| | Simon J. Oh | 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 11 March 2005.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-6, 10, 16-18 and 20-32 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-6, 10, 16-18 and 20-32 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment, response, petition for extension of time, request for continued examination, and change in power of attorney, all received on 11 March 2005.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6, 10, 16-18, and 20-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz *et al.* (PCT Publication No. WO 92/15285)

The Lentz *et al.* document discloses controlled-release starch compositions (See Abstract). The compositions comprise a melt made from a starch/water mixture and an active ingredient. The starch is processed in such a way as to eliminate a granular starch structure, rendering it "destructured", which can include heating the starch melt above the glass transition temperature (See Page 11, Line 8 to Page 12, Line 30; and Page 17, Line 34 to Page 18, Line 15). This composition is processed under shear at temperatures ranging from about 80°C to about 24°C (See Abstract). This allows for greater compressibility in the formation of tablets (See Page 15, Lines 8-14). Various types of drugs, either water-soluble or -insoluble, may be incorporated into the disclosed controlled-release starch matrices (See Page 15, Line 25 to Page 16, Line 39). Various types of dosage forms, including tablets, capsules, beads, granules,

powders, and solids may be formulated from the compositions. Processing techniques that may be used to produce such dosage forms include wet and dry granulation, injection molding, thermoforming, extrusion, co-extrusion, and cast molding (See Page 26, Line 29 to Page 27, Line 21). Release profiles are given which show the release of an active ingredient over a period of 24 hours. The release profile of the active ingredient appears to follow a lapidus function (See Figures 2 & 3).

Although the disclosed release profiles only show drug release up to a period of 24 hours, the amount of drug released in some figures remain under 100%. It is the position of the examiner that drug release can continue beyond 24 hours and that this release profile is due to the insolubility of the amorphous starch matrix. Thus, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 11 March 2005 have been fully considered but they are not persuasive.

The examiner does not interpret the prior art as being solely limited to what has been disclosed in the examples of the Lentz *et al.* reference. The examiner must take the broadest reasonable interpretation of both the claims and the prior art. It is the position of the examiner that one of ordinary skill in the art, giving both the prior art and the claims in their present form their broadest reasonable interpretation, would find the claimed invention obvious in view of the prior art. See MPEP § 2111 and 2123. The examiner must also consider what has been taught by the prior art apart from what is only disclosed in given examples. The Lentz *et al.* reference

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has disclosed the use of co-extrusion as a method of manufacture, as well as a level of destructure-urization beyond the glass transition temperature of the ingredients. As such, all pending claims are presently rejected.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
Art Unit 1615

sjo

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600